K034004

MAR - 3 2004

510(k) Summary

Submitter's Name	Gyrus ENT LLC
Submitter's Address	2925 Appling Road, Bartlett, TN 38133
Submitter's Phone Number	(901) 373-0200
Contact Person	Alicia E. Farage
Date Revised:	February 19, 2004
Proprietary Name:	Diego™ RF Dissector and Drill System
Common Name:	Electrical Surgical Drill/Shaver
Classification Name:	Ear, Nose and Throat electric or pneumatic surgical drill (§ 874.4250)
Classification	Class II
Classification Panel	Ear, Nose, Throat
Device Product Code	77 ERL

Subject Device Description

The new Diego RF Powered Dissector and Drill System Console is identical to the console cleared in 510(k) # 020594 (3.08.02). However an additional panel was added to operate the current handpieces with new RF blades that can provide coagulation in addition to powered dissection. Other than coagulation during procedures, there are no new indications for use.

Applicable 510(k)s – Predicate Devices

Device	Manufacturer	FDA Clearance
Diego Powered Dissector and Drill System	Gyrus ENT LLC Bartlett, TN 38133	K020594
Smith & Nephew Dyonics® ElectroBlade™ Arthroscopy System	Smith & Nephew, Inc. Endoscopy Division Andover, MD 001810	K994365 K012314 K031675
Gyrus ENT Plasmacision	Gyrus ENT LLC Bartlett, TN 38133	K021777
Arthrocare ENTec Coblator Surgery System	Arthocare Corporation Sunnyvale, CA 94085	K030108
Surgitron IEC II	Ellman International Hewlett, NY 11557	K001986

Subject Device Intended Use

The Diego RF Powered Dissector and Drill System's intended use is the cutting and removal of bone and tissue in general ENT, Head & Neck, and otoneurologic procedures.

Sinus applications include:

- ethmoidectomy/sphenoethmoidectomy
- polypectomy
- septoplasty and
- procedures such as
  - the removal of septal spurs
  - antrostomy,
  - frontal sinus trephination and irrigation
  - frontal sinus drill-out
  - endoscopic DCR
  - trans-spehnoidal procedures

Nasopharyngeal/laryngeal procedures would comprise

- adenoidectomy:
- laryngeal lesion de-bulking
- laryngeal polypectomy
- tracheal procedures
- tonsillectomy

Head & neck procedures would encompass:

- soft tissue shaving
- rhinoplasty (narrowing of the bony vault and revision of the bony pyramid)
- removal of fatty (adipose) tissue (lipodebridement) in the maxillary and mandibular regions of the face
- acoustic neuroma removal

Otology procedures would include

- mastoidectomy
- mastoidotomy

Comparison Chart of Power Ratings

Diego RF Powered Dissector and Drill System
Vs.
Gyrus ENT Plasmacision vs. Arthrocare ENTec Coblation Plastma Surgery vs. Ellman Surgitron IEC

	Diego RF Gyus ENT (K034004)	**Gyrus ENT Plasmacision (K021777)**	**Arthrocare ENTec Coblation Plastma Surgery (K030108)**	**Ellman Surgitron IEC (K001986)**
Intended Use	General ENT, Head & Neck, and Otoneurologic Procedures	General ENT, Head & Neck, and Otoneurologic Procedures	General ENT Procedures	General ENT Procedures
Functions	Tissue Removal and RF Coagulation	Tissue Removal and RF Coagulation	Ablation, Resection and Coaguration of Soft Tissue and Hemostatis of Blood Vessels	Resection, Ablation, and Coagulation of Soft Tissues and Hemostasis of Blood Vessels
Default Power Rating	10 Watts	30 Watts	284 Watts	Cut 100 Watts Cut/Coag 75 Watts Hemo 35 Watts Fulgurate 35 Watts Bipolar 40 Watts
Maximun Power Rating	40 Watts	40 Watts	284 Watts	100 Watts

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 3 2004

Gyrus ENT
c/o Alicia E. Farage
Manager Clinical/Regulatory Affairs
2925 Appling Road
Bartlett, TN 38133

Re: K034004
Trade/Device Name: Diego™ RF Powered Dissector and Drill System
Regulation Number: 21 CFR 874.4250
Regulation Name: ENT electric or pneumatic surgical drill
Regulatory Class: Class II
Product Code: ERL
Dated: December 22, 2003
Received: December 24, 2003

Dear Ms. Farage:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K034004

Indications for Use:

510(k) Number:

Device Name: **Diego™ RF Powered Dissector and Drill System**

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- procedures such as
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Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K034004